No. 87-1194

In the Supreme Court of the United States

OCTOBER TERM, 1987

COSMETIC, TOILETRY AND FRAGRANCE ASSOCIATION, PETITIONER

v.

PUBLIC CITIZEN, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a color additive that poses only a de minimis risk of cancer is "unsafe" within the meaning of the Color Additive Amendments of 1960 to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 376(b)(5)(B).

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OPINION BELOW

The opinion of the court of appeals (Pet. App. 1a-34a) is reported at 831 F.2d 1108.

JURISDICTION

The judgment of the court of appeals (Pet. App. 185a-186a) was entered on October 23, 1987. The petition for a writ of certiorari was filed on January 19, 1988. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. The Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. 301 *et seq.*, establishes a comprehensive regulatory scheme governing use of color additives in cos-

metic and drug products. In essence, the scheme prohibits use of color additives unless they have been determined to be safe by the Secretary of Health and Human Services. In the Color Additive Amendments of 1960, 21 U.S.C. 376, Congress added a provision to the FDCA commonly known as the Delaney Clause, patterned after a similar clause in the Food Additives Amendment of 1958, 21 U.S.C. 348. That clause provides that color additives "shall be deemed unsafe" for non-ingested uses if the Secretary finds, in "tests which are appropriate for the evaluation of the safety of additives for such use," that they "induce cancer in man or animal." 21 U.S.C. 376(b)(5)(B)(ii).

2. This case involves two dyes, Orange No. 17 and Red No. 19, that the Commissioner of the Food and Drug Administration (FDA), as the Secretary's designee, approved for external uses.[1] The FDA determined that, although these two dyes caused cancerous tumors in animals in laboratory tests when the animals were exposed to the "maximum tolerated dose,"[2] they posed no actual health risk to humans. Pet. App. 43a, 85a-90a, 106a, 154a-159a. In so finding, the FDA relied on an analytical technique known as "quantitative risk assessment," which extrapolates from laboratory data and analyzes human safety based on projected conditions of actual use of the relevant substance. The risk assessment technique used by the FDA greatly overstates the risk to humans, because the

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[1] These dyes have been in use for years, primarily in cosmetics. In 1983, the FDA ended provisional listing of these dyes for applications involving ingested use, *e.g.*, lipstick. 48 Fed. Reg. 5262, 13976. This case involves only external use of the dyes.

[2] The maximum tolerated dose is the greatest amount that would "assure that the test animals are challenged but not killed by the noncarcinogenic toxic effects of high doses of a substance." Pet. App. 52a.

FDA relies on a "worst case" assumption at each stage of the analysis. Accordingly, the risks are not actuarial risks; rather, they are theoretical figures built on assumptions designed greatly to overstate the risk from use of the dyes. In this case, the FDA found that the two dyes posed cancer risks of 1 in 19 billion and 1 in 9 million.[3] In practical terms, this means that in all likelihood no person would ever contract cancer from use of these dyes and that there is no discernible threat to human safety from their use.

Based on its finding that the dyes posed essentially no risk of cancer in humans, the FDA approved the dyes for non-ingested uses. In its initial decision, the FDA reasoned that even though the dyes had been found to "induce" cancer in laboratory animals, the Delaney Clause should be read as containing a de minimis exception for color additives found by experts to be safe for humans. Pet. App. 79a-85a, 148a-154a. The agency observed that in 1958 there were only a small number of known carcinogens, and that Congress did not foresee that scientific testing techniques would advance to the point where researchers could determine that there are a broad range of substances present in many foods and other products that, although technically carcinogens, are present in such amounts that they pose only a de minimis risk of cancer. Recognizing a de minimis exception to the Delaney Clause, the FDA concluded, would therefore be consistent with Congress's understanding that the Delaney Clause would have no appreciable effect on the food supply, while also assuring that the food supply would not be contaminated by substances presenting a material risk of cancer. *Id.* at 83a-85a, 152a-154a.

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[3] These figures were developed by an expert scientific review panel composed of Public Health Service scientists convened by the FDA to provide an outside analysis. Before arriving at these figures, that panel initially decided that quantitative risk assessment techniques were appropriate for analysis of the dyes at issue.

When the government filed its brief in the court of appeals, the FDA issued two new *Federal Register* notices clarifying its earlier reasoning for approving the color additives. Pet. App. 173a-178a; *id.* at 179-184a. In these notices, the FDA explained that the statutory term "to induce cancer" is a term of art; that the agency's prior statements that these color additives had "induced" cancer in laboratory test animals should be read only as an observation that, under controlled scientific conditions designed to amplify the effect of the color additives on laboratory animals, use of the maximum tolerated dose could lead to cancer in such animals; and that the conclusion that the high-dosage use of these two color additives could lead to cancer in laboratory animals is not equivalent to the conclusion that the normal use of these additives would "induce" cancer in man or animals within the meaning of the FDCA. *Id.* at 176a-177a, 182a-183a. Any other construction of the Act would not be faithful to the intent of Congress, the FDA concluded, because Congress did not expect that the enactment of the original Delaney Clause in the Food Additives Amendment of 1958 would seriously affect the food supply. As the FDA summarized, "[w]hen a substance causes only a de minimis level of risk in animals, it cannot be said to induce cancer in animals within the meaning of the Delaney Clause." *Id.* at 175a, 181a.

3. Respondents Public Citizen *et al.*[4] challenged the FDA's decisions in the court of appeals. Respondents did not challenge the FDA's finding that the color additives at issue posed only a de minimis risk of causing cancer in humans. Instead, respondents argued that the Delaney Clause required any substance that is found to cause

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[4] We will hereafter use the term "respondents" to refer only to the non-federal respondents.

cancer in humans or animals to be considered "unsafe," even if the risk that a human would suffer cancer is virtually nonexistent. Petitioner Cosmetic, Toiletry and Fragrance Association, a trade association that includes the major users of the color additives at issue, intervened to support the FDA's decision to approve the additives.

The court of appeals reversed the FDA's decision (Pet. App. 1a-34a). The court agreed with the FDA that the risks posed by the two color additives at issue were trivial. *Id.* at 7a. Nonetheless, the court rejected petitioner's argument that there is a general de minimis exception to the Color Additive Amendments of 1960. The court concluded that the text and legislative history of those Amendments foreclose any such exception. *Id.* at 8a-27a. The court also rejected the FDA's argument that the additives under dispute do not "induce" cancer within the meaning of the Color Additive Amendments of 1960. *Id.* at 27a-30a. The court held that Congress did not permit the FDA to determine that a dye does not "induce" cancer within the meaning of the Delaney Clause if it causes cancer in laboratory test animals under any circumstances. *Id.* at 30a.

ARGUMENT

Although we disagree in part with the court of appeals' decision, and are troubled by some of its implications, we do not believe that further review is warranted at this time, for several reasons.

1. There is no square conflict among the circuits on the question presented in the petition.[5] The decision below

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[5] The decision below also does not conflict with this Court's decisions in *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914), or *Permian Basin Area Rate Cases*, 390 U.S. 747 (1968).

does not conflict with the Sixth Circuit's decision in *Scott* v. *FDA*, 728 F.2d 322 (1984). There, a private party challenged the FDA's decision to approve a color additive on the ground that the dye contained minute quantities of a chemical impurity that had been found to cause cancer in test animals, even though the color additive itself, when considered as a whole, did not have that effect. The court held that the FDA's decision to approve the dye was consistent with the text of the Color Additive Amendments of 1960, which focuses on the effect of the additive, rather than its constituent elements. 728 F.2d at 325. By contrast, in this case the court of appeals found that the dyes themselves induce cancer within the meaning of the Color Additive Amendments of 1960.

The decision below also does not conflict with *Monsanto Co.* v. *Kennedy*, 613 F.2d 947 (D.C. Cir. 1979). The court held there that the FDA has the authority to apply a de minimis exception to the definition of a food additive in the FDCA, 21 U.S.C. 321(s), and to ignore trace amounts of a substance that migrate from a container into food as long as the presence of those trace amounts does not pose a significant risk of injury to the public health. 613 F.2d at 955. As the court below explained, however (Pet. App. 22a-23a), *Monsanto* did not expressly consider the relationship between the de minimis principle endorsed in that decision and the Delaney Clause. In sum, while petitioner correctly notes (Pet. 28) that *Monsanto* and *Scott* lead to anomalous results when considered along with the ruling

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Neither case involved the Food Additives Amendment of 1958 or the Color Additive Amendments of 1960, and neither decision holds that a federal agency may create a de minimis exception as a general rule of administrative law.

in this case,[6] at present there is no express conflict among the circuits on the question presented in the petition.[7]

2. Petitioner's efforts to show that the decision below is in error rest almost entirely (Pet. 15-20) on the legislative history of the Food Additives Amendment of 1958, 21 U.S.C. 348, the predecessor of the Color Additive Amendments of 1960, 21 U.S.C. 376. As the court of appeals pointed out, however (Pet. App. 25a-27a), this case does not involve the Food Additives Amendment of 1958, and the context in which that Amendment was enacted is "clearly different" from the context surrounding the Color Additive Amendments of 1960 (*id.* at 26a).[8] The

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[6] Application of the Delaney Clause without a de minimis exception would actually increase the risks to the public health, as the court of appeals acknowledged. Pet. App. 10a-11a. For example, suppose there were two substances available for a particular use. The first is carcinogenic, but poses only a negligible actual risk; the other is not carcinogenic, but is measurably more likely to be harmful to the public than the first substance, even though it is still regarded as safe by the FDA. Under those circumstances, a decision to ban the first substance, thereby exposing the public to the second one, has the effect of increasing the danger to the public health.

[7] In a case such as this one the absence of a clear conflict is not necessarily dispositive. Because the FDA can always be sued in the District of Columbia, once the District of Columbia Circuit has ruled against the FDA on a question, it may be that all future suits against the agency will be brought in that circuit and a conflict among the circuits will never arise. The absence of such a conflict therefore is only one factor influencing our position that review by this Court is not warranted. A similar challenge to the FDA's approval of two other color additives is now pending in the Third Circuit. *Public Citizen* v. *FDA*, No. 87-3507. Briefing in that case has been postponed pending resolution of the certiorari petition in this case.

[8] As the court of appeals noted, "we may safely say that [the] proponents [of the food additive Delaney Clause] could not have regarded as trivial the social cost of banning" considerable portions of the American diet. Pet. App. 26a-27a. The legislative history of the

arguments offered by petitioner are therefore more appropriately considered in a case arising under the Food Additives Amendment of 1958.

3. Petitioner's attempts to demonstrate that the decision is important likewise rest almost exclusively on the Food Additives Amendment of 1958. Petitioner contends (Pet. 22-26) that the decision below will necessarily apply to the Delaney Clause in the Food Additives Amendment of 1958, and will therefore jeopardize the nation's food supply. That prediction, however, is premature. The court of appeals expressly limited its decision to the Color Additive Amendments of 1960 (see Pet. App. 25a-27a). The court apparently found that the legislative history of the Food Additives Amendment of 1958, upon which petitioner primarily relies (see Pet. 15-18), was not relevant to the question in this case. And the court noted that, under the *Monsanto* case, there may be a de minimis exception to the definition of a food additive under 21 U.S.C. 321(s) (the exception for substances "generally recognized as safe"), which would not apply in a case concerning color additives. The court of appeals' decision therefore leaves open the possibility that it will uphold a decision by the FDA finding that a food additive that entails a de minimis risk of cancer to man is not subject to the Delaney Clause of the Food Additives Amendment of 1958. Thus, the court of appeals' ruling does not appear to have the serious

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Food Additives Amendment of 1958 bears out the court of appeals' assessment. The Senate Committee Report states that "we believe the bill reads and means the same with or without the inclusion of the [Delaney] clause referred to. This is also the view of the Food and Drug Administration." S. Rep. 2422, 85th Cong., 2d Sess. 11 (1958). It is most unlikely that Congress foresaw that the food additive Delaney Clause, when combined with an advancing technology, would call into question large portions of the food supply in which trace amounts of carcinogenic substances can now be found.

and immediate consequences for the nation's food supply that petitioner attributes to it. Review by this Court would be more appropriate after the lower courts have examined the issue of de minimis risks under the Food Additives Amendment of 1958.

4. Finally, review by this Court of the question presented in the petition would be premature because the government's views are still undergoing refinement. In general, we believe that quantitative risk assessment is an appropriate tool to use in applying statutes so that they do not produce arbitrary and unintended results in light of advancing scientific knowledge. But the government has only recently begun to consider the appropriate role of quantitative risk analysis in applying the Delaney Clause. The government's views in this case, for example, are set forth in two sets of documents, with the second building on and clarifying the first. See pages 2-3, *supra*. Although the court of appeals considered both the initial explanation and the clarification, it would be preferable to wait for a case where the record was developed in light of the FDA's most current and authoritative application of the statute. In addition, another agency, the Environmental Protection Agency, is now also in the process of determining whether a de minimis exception is applicable to the pesticides it regulates (see, *e.g.*, 21 U.S.C. 364a) if they become food additives. See *Federal Insecticide, Fungicide, and Rodenticide Act: Hearings on S. 1516 Before the Senate Comm. on Agriculture, Nutrition, and Forestry*, 100th Cong., 1st Sess. Pt. 2, at 34, 39-40 (1987) (Ass't Adm'r John Moore). In short, the federal government is in the process of giving further consideration to the issues raised by this case. Review by this Court should wait until that process comes to rest.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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